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10/568,101	02/13/2006	Toshihiro Mori	06491217PUS1	7811

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EXAMINER	
WILDER, CYNTHIA B	
ART UNIT	**PAPER NUMBER**
1637	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/568,101	MORI ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-36* is/are pending in the application.

4a) Of the above claim(s) *35 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed August 16, 2007 is acknowledged and has been entered. Claims 1, 2, 10, have been amended. Claim 3 has been canceled. Claims 1-36 are pending. Claims 35 and 36 are withdrawn from consideration as being drawn to a non-elected invention. All of the arguments have been thoroughly reviewed and considered but are deemed moot in view of the new ground(s) of rejections necessitated by Applicant's amendment of the claims. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

This action is made FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

3. Applicants affirm the election, with traverse of the invention of Group I, but states that it would not be an undue burden to search a reagent kit and apparatus depending from claims within the elected group. Applicants assert that they do not agree that Muller et al discloses the "special technical feature of the presently claimed invention.

The arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow. In response to Applicant's arguments that a serious search burden does not exist, the Examiner maintains that the inventions of Groups II and III would impose a search burden on the examiner if not restricted from the invention of Group I because the different inventions are capable of functioning irrespective of each other. Likewise, the product of invention II and III are broader in

scope than the method of invention I and hence encompasses a review of numerous literatures that may are may not be associated with the method of invention I. For example, a search on one database of the invention of Group II resulted in over 9300 documents. The searches of the different inventions are not coextensive.

In response to Applicant's arguments concerning the Muller reference, it is noted that the reference teaches a reagent kit (see entire patent and claims 34-44) as broadly written. Applicants' arguments are not persuasive. Accordingly, the requirement is still deemed proper and is therefore made FINAL.

Previous Rejections

4. The objection to the priority claim is withdrawn in view of Applicant's submission of translated document and arguments. Accordingly, the effective filing date of the present application is September 8, 2004. The objection to the Information disclosure statement is withdrawn in view of Applicant's arguments. The prior art rejection under 35 USC 102(b) as being anticipated by Woodard et al is withdrawn in view of Applicant's amendment. The prior art rejection under 35 USC 102(b) as being anticipated by Su et al is withdrawn in view of Applicant's amendment. The prior art rejection under 35 USC 102(a) and 35 USC 102(e) as being anticipated by Iwaki et al is withdrawn in view of Applicant's effective filing date and perfection of priority claim. The prior art rejection under 103(a) as being unpatentable over Woodward in view of Su et al and further in view of Sigma data sheet is withdrawn in view of Applicant's amendment of the claims. The double patenting rejections are maintained and discussed below.

Double Patenting

5. Once again the double patenting rejections as recited on pages 16-30 of the prior office action mailed on 05/16/2007. Applicants traverse the rejections on the ground that that the request issue of a Notice of Allowance in the present application and will address any possible double patenting rejections at a later date.

This argument is not found persuasive because the instant invention is not deemed in condition for allowance. Accordingly, the double patenting rejections as recited in the prior Office action are maintained.

New Ground(s) of Rejections

THE NEW GROUND(S) OF REJECTIONS WERE NECESSITATED BY APPLICANTS' AMENDMENT OF THE CLAIMS:

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-2, 4-14,18-31, 33, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Su et al {herein, Su (A)} (WO 97/08547, cited in prior Office action) and Su et al {herein, Su (B)} (5,804,684, cited in prior Office action) and further in view of Kappel et al (20040259162, cited in prior Office action) and Sigma Data Sheet (citation made of record in prior Office action). Regarding claims 1, Regarding claim 1, Su (A) teaches a method for isolating and purifying a nucleic acid, comprising the step of: (1) contacting a sample solution containing nucleic acid to a solid phase to adsorb the nucleic acid onto the solid phase contacting a washing solution to the solid phase to wash the solid phase in such a state that the nucleic acid is adsorbed; and (3) contacting an elution solution to the solid phase to desorb the nucleic acid, wherein the sample solution containing nucleic acid contains further addition of a water soluble organic solvent (see pages 3-10 and 22-24) and polyethylene glycol (PEG), which is an example of an antifoaming agent (see page 10, first full paragraph).

Su (B) teaches a method similar to that of Su (A) for isolating nucleic acids, wherein the method comprises contacting a sample solution to a solid phase in such a state that the nucleic acid is absorbed and contacting an elution solution to the solid phase to desorb the nucleic acid (see example 1, col. 10).

Neither Su (A) or Su (B) expressly teach wherein the method comprises an anti-foaming agent along with a surface-active agent.

Kappel et al teach a method and apparatus for solid phase lysis and capture of nucleic acids. Kappel teach wherein a lytic reagent is added to cells to extract the nucleic acid, said reagent comprises may comprise a chaotropic agent, buffer, bulking agent, process enzymes, enzymatic inhibitors or an antifoaming agent, wherein said antifoaming agent include antifoam A, antifoam B and antifoam C, which are all silicon-based antifoaming agents (see attached product data sheet at page 2 for antifoam information (0109). Kappel teach wherein the lytic reagent further comprises a surface-active agent (surfactant) (see 0110-0113). Kappel teaches that the antifoaming agent is added to prevent excessive foaming or frothing during lysis (0117). Kappel additionally teach that the invention is relatively fast, efficient for lysing cells and eliminates the need to centrifuge a cellular solution to remove insoluble material (0007).

Therefore, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have added a surfactant and antifoaming agent in the presence of a water soluble organic solvent in the pretreatment solution of Su (A) and Su (B) for the obvious benefit of preventing excessive foaming or frothing during lysis and for the additional benefit of eliminating the need for centrifugation to remove insoluble material as suggested by Kappel.

Regarding claims 2, Su (A) teaches wherein the sample solution containing nucleic acid is prepared by further addition and mixing of a pretreatment solution containing a nucleic acid stabilizer, wherein said stabilizer is a chelating agent (EDTA), and wherein said wherein said stabilizer is a chelating agent, chaotropic agent, a protease or a buffer (pages 9-10, Example 1).

Regarding claim 4, Kappel et al teach wherein the antifoaming agent includes antifoam A, antifoam B and antifoam C, which are all silicon-based antifoaming agents (see attached product data sheet at page 2 for antifoam information (0109, cited in prior Office action).

Regarding claims 5-8, Su (B) teach wherein the stabilizer is a chelating agent at a concentration of 10 mM (col. 10, Example 1) or a reducing agent such as a mercapto-compound (DTT) at a concentration of 25 mM (col. 10, Example 1).

Regarding claim 9, Kappel et al teach wherein the chaotropic agent is a guanidium salt (0116).

Regarding claim 10, Su (A) teaches wherein the sample solution containing nucleic acid is prepared by further addition of a water-soluble organic solvent, such as ethanol, isopropanol or acetone (page 10, lines 8 and 9).

Regarding claim 11, Su (A) teaches wherein the solid phase is a solid phase containing silica (page 11, line 18).

Regarding claims 12-13, Su (A) teaches wherein the solid phase is a solid phase containing an organic macromolecule, wherein said organic molecule has a polysaccharide structure (page 7, line 8).

Regarding claim 14, Su (A) teaches wherein the organic macromolecule is acetyl cellulose (page 7, lines 9-10).

Regarding claim 18, Su (B) teaches wherein the organic macromolecule is regenerated cellulose (column 7).

Regarding claim 19-22, Su (A) teaches wherein the solid phase is a porous membrane having an average pore diameter of 1 to 100 microns in diameter (page 7, lines 1-100).

Regarding claim 23, Su (A) teaches wherein the solid phase is nonporous (page 25, line 6 and 7).

Regarding claim 24 and 25, Su (A) teaches wherein the solid phase is coated beads and wherein said beads are magnetic beads (page 25, lines 5-7).

Regarding claim 26, Su (A) teaches wherein the adsorption and desorption of nucleic acids are carried out using a cartridge for isolating and purifying a nucleic acid, which houses the solid phase in a container having at least two openings (col. 25 and section entitled "Apparatuses of the Invention" at pages 41-46).

Regarding claim 27 and 28, Su (A) teaches wherein the adsorption and desorption of nucleic acid are carried out using a unit for isolating and purifying a nucleic acid, which has a solid phase, a container having at least two opening which house the solid phase and an apparatus for generating the pressure different, which is connected to one of the openings of the container (page 11-12 and section entitled "Apparatuses of the Invention" at pages 41-46).

Regarding claim 29, Su (B) teaches the embodiments of claim 27, wherein the apparatus for generating the pressure difference is an apparatus for pressure reduction (see col. 16).

Regarding claim 30, Su (B) teaches wherein the apparatus for generating the pressure difference is connected to one of the opening of the container in a freely detachable manner (col. 16).

Regarding claim 31, Su (B) teaches the method for isolating and purifying a nucleic acid according to claim 27, which comprises the step of: (2a) preparing a sample solution containing nucleic acid from a sample and infusing the sample solution containing nucleic acid into one of the openings of the container housing the solid phase, the container having at least two openings; (2b) making the inner area of the container into a pressurized state by using the apparatus for generating the pressure difference being connected to the one of the openings of the container and contacting the infused sample solution containing nucleic acid to the solid phase by discharging the sample solution from another opening of the container to adsorb nucleic acid onto the solid phase; (2c) detaching the apparatus for generating the pressure difference from the one opening of the container and infusing a washing solution into the one opening of the container; (2d) making the inner area of the container into a pressurized state by using the apparatus for generating the pressure difference being connected to one of the openings of the container and discharging the infused washing solution from another opening of the container to contact the washing solution to the solid phase to wash the solid phase; (2e) detaching the apparatus for generating the pressure

difference from the one opening of the container and infusing an elution solution into the one opening of the container; and (2f) making the inner area of the container into a pressurized state by using the apparatus for generating the pressure difference being connected to the one of the openings of the container and discharging the infused elution solution from another opening of the container to desorb the adsorbed nucleic acid from the solid phase and discharge nucleic acid outside the container (col. 15 and 16 and Figures 1 and 2).

Regarding claim 33, Su (B) teaches wherein the washing solution is a solution containing 20 to 100% by mass of methanol, ethanol, isopropanol or n-propanol (bottom of col. 3 to col. 4, line 45 and Example 1).

Regarding claim 34, Su (B) teaches wherein the elution solution is a solution having a salt concentration of not more the 0.5 mol/L (col. 10, Example 1).

8. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Su (A) and Su (B) in view of Kappel et al as previously applied above and further in view of Seto et al (20050045538). Regarding claims 14-17, Su (A) and (Su (B) in view of Kappel et al teach a method for isolating and purifying a nucleic acid as previously described above.

Su (A) and Su (B) in view of Kappel et al do not expressly teach wherein the organic macromolecule is subjected to a saponification treatment of the mixture of acetyl cellulose having different acetyl values.

Seto et al teach an organic macromolecule wherein the organic macromolecule is acetylcellulose having different acetyl values and wherein the organic macromolecule is obtained is saponification (0058, 0094-0096). Seto et al teach that the saponification process promotes formation of a porous film (0094) for solid phase extraction.

One of ordinary skill in the art at the time of the claimed invention would have been motivated to have modified the isolation method of Su (A) and Su (B) in view of Kappel to encompass a saponification process of the organic macromolecule for the obvious benefit of promoting efficient formation of a porous film for solid phase extraction as taught by Seto et al.

9. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Su (A) and Su (B) in view of Kappel as previously discussed above and further in view of Natrajan et al (20020076823). Regarding claim 32, Su (A) and Su (B) in view of Kappel teach a method for isolating and purifying nucleic acid as previously described above.

Su (A) and Su (B) in view of Kappel et al do not expressly teach wherein DNase is added to the solid phase and then washing the solid phase with the washing solution.

Natrajan et al teach a method wherein DNase is added to the solid phase prior to the addition of a wash solution (0213). Natrajan et al teach that the addition of the DNase solution facilitates release of the nucleic acid from the solid phase (0213). Therefore, one of ordinary skill in the art at the time of the claimed invention would have been motivated to apply DNase to the solid phase prior to the washing step in the

isolation methods of Su (A) and Su (B) in view of Kappel et al for the obvious benefit of facilitating release of the nucleic acid from the solid phase as suggested by Natrajan et al.

Conclusion

10. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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